

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional) 12730-11

I hereby certify that this correspondence is being electronically deposited pursuant to 37 CFR 1.8(a) with the United States Patent and Trademark Office through the Electronic Filing System, on the below date:

On: September 7, 2010Signature: /Jason W. Schigelone/Typed or printed name: Jason W. Schigelone, Reg. No. 56,243

Application Number

10/642,513

Filed

August 15, 2003For: Stent and Method of Forming a Stent with Integral BarbsInventors Osborne et al.

Art Unit

3774

Conf. No.

3839

Examiner

William H. Matthews

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five(5) pages may be provided.

I am the:

☐ Applicant/Inventor.

/Jason W. Schigelone/

Signature

☐ Assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

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Registration No. 56,243.

Jason W. Schigelone

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Note: Signatures of all inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.*

September 7, 2010

Date

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CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence, including recited attachments, is being electronically transmitted to the United States Patent and Trademark Office on the below date:

Date: September 7, 2010 Name: Jason W. Schigelone, Reg. No. 56,243 Signature: /Jason W. Schigelone/

Attorney Docket No.: 12730-11

Client Ref. No.: PA-5327-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Osborne <i>et al.</i>)	
)	
Serial No.: 10/642,513)	Examiner: William H. Matthews
)	
Filing Date: August 15, 2003)	Group Art Unit No.: 3774
)	
For: Stent and Method of Forming a Stent with Integral Barbs)	Confirmation No.: 3839
)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants request review of the file of the above-identified application, for the reasons stated in the attached sheets. No amendments to the claims are filed with this request. Applicants also file a Notice of Appeal along with this request. No more than five (5) pages are provided.

I. Background

A. The Claims

The present claims recite, among other things, a wire having 1) at least one integrally-formed barb that 2) points in a predetermined direction at an angle relative to a longitudinal axis of the stent, where 3) the integral barb is unbent with respect to the wire and is free of weakening due to bending. This is the **second** pre-appeal request made in this matter on the same primary reference.

B. Decision By The Board of Patent Appeals and Interferences

On October 14, 2009, the Board of Patent Appeals and Interferences ("the Board") reversed the Examiner's rejection of the pending claims as anticipated by U.S. Patent No. 5,800,526 ("Anderson"). In that decision, after considering Anderson and the Examiner's arguments regarding

Anderson's disclosure, the Board held ***"the Examiner erred in determining that the integral barbs of Anderson are unbent with respect to the stent wire."*** See Board Decision at p. 6 (emphasis added). The Board noted the pending claims all recite at least one barb that is *unbent* with respect to a wire, but that ***"Anderson specifically teaches that the barbs 20 bend outwardly when the stent 10 expands radially."*** See *id.* at p. 5 (emphasis added). In addition, the Board held ***"the barbs 20 of Anderson are not necessarily unbent with respect to the stent wire."*** See *id.* (emphasis added).

C. The Present Rejection

Claims 45-64 are pending in the present application. Claims 47, 51, 52, 54-57, 59, 63, and 64 are withdrawn. Claims 45, 46, 48-50, 53, 58, and 60-62 are presently rejected under 35 U.S.C. § 103 as allegedly obvious – again, in view of Anderson.

The claims in the present application have not been amended since the Board's decision. Notably, the present claims still recite, among other things, integral barbs that are unbent with respect to a stent wire. This is a feature that the Board explicitly held Anderson does not disclose. Indeed, the Board held that the Examiner's conclusion to the contrary was an error – as a matter of law.

II. Argument

A. The Present Rejection Blatantly Disregards The Board's Decision.

The Examiner's arguments in support of the present obviousness rejection are essentially the same arguments that the Board already considered and rejected. For example, the Examiner states "Anderson thus appears to teach barbs unbent with respect to the stent struts," (*see* Final Office Action dated June 22, 2010 ("Final Office Action") at p. 4), and Figure 7 of Anderson shows barbs that are unbent with respect to a wire (*see* Final Office Action at pp. 2, 4, and 5). These arguments completely disregard the Board's clear findings regarding Anderson:

[T]he Examiner points to Figures 4-7 of Anderson to show that because both wire bends 18 and barbs 20 face outwardly, the barbs 20 are not bent with respect to the wire. In other words, the Examiner appears to take the position that because material has been removed in areas of the barbs 20, during expansion of the stent 10 the wire 18 will bend at these regions such that barbs 20 will be oriented outwardly but will not bend with respect to the stent wire. ***We disagree with the Examiner's position . . .***

See Board Decision at p. 4 (internal citation omitted) (emphasis added).

[T]he Examiner erred in determining that the integral barbs of Anderson are unbent with respect to the stent wire."

See *id.* at p. 6 (emphasis added). The Examiner's suggestion that Anderson discloses, or appears to disclose, unbent barbs is foreclosed by the Board's decision to the contrary, and the Examiner's continued reliance on this argument is clear and inexcusable error.

According to the Examiner, Anderson's disclosure contains a "contradiction." See Final Office Action at p. 2. In particular, the Examiner states, "[t]he [Anderson] specification describes the barbs being bent outward while Figure 7 shows the 'bent' state, and the barbs 20 are not bent with respect to the arches 18." As explained above, however, the Board already considered the Anderson specification and Figure 7 (which allegedly contain a contradiction) and determined that Figure 7 **does not** show unbent barbs. Thus, the Board already resolved any so-called "contradiction" in Applicants' favor. The fact that the Examiner still sees a contradiction is just more evidence that he is ignoring the Board's decision.

The Examiner's disregard of the Board's recent decision in this case is one more clear error. See Board Decision at p. 6 ("the Examiner erred in determining that the integral barbs of Anderson are unbent with respect to the stent wire.")

B. The Examiner Has Failed To Establish *Prima Facie* Obviousness.

The Examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). When the examiner fails to meet that burden, without more, the applicant is entitled to a patent. *Id.* To establish a *prima facie* case of obviousness based on a combination of references, the examiner must articulate the particular basis for the conclusion that the combination would have been obvious. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006). An obviousness analysis must be explicit and cannot be sustained by mere conclusory statements. *KSR v. Teleflex*, 550 U.S. 398, 418 (2007). Rather, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *KSR v. Teleflex*, 550 U.S. 398, 418 (2007).

To prevent the use of hindsight, the examiner must identify some reason or motivation one of ordinary skill in the art would have had to choose particular references for combination. *KSR v. Teleflex*, 550 U.S. 398, 418 (2007); *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (reversing Board's finding of obviousness as clearly erroneous due to failure to provide any proper motivation to combine references.). Hindsight is inferred when the fact-finder fails to explain the specific understanding or principle that would have motivated a skilled artisan to combine particular references. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006); *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998).

1. Anderson Does Not Disclose, Teach, or Suggest The Present Invention.

The Examiner asserts that the present claims would have been obvious in view of the combination of Anderson and U.S. Patent Application Publication No. 2001/0027339 ("Boatman"). According to the Examiner, "Anderson . . . appears to teach barbs unbent with respect to the stent struts" – an assertion that was rejected by the Board. With respect to the "predetermined direction" feature of the present claims, the Examiner argues "Anderson desires the barbs to point outwardly in response to a bending action, and outwardly is a direction." The claims recite a "predetermined direction," however, which is not satisfied by any arbitrary, undetermined direction. The Examiner's suggestion that **any** direction is a predetermined direction divorces this feature of any patentable weight and is improper.

Thus, Anderson fails to disclose at least a wire having an integrally-formed barb that points in a predetermined direction, or a wire having an integral barb that is unbent with respect to the wire and is free of weakening due to bending.

2. Boatman Does Not Make Up For Anderson's Deficiencies.

Next, the Examiner combines Boatman "to ensure the barbs in Anderson are free of unnecessary bending stresses." The Examiner fails to explain why one of ordinary skill in the art would have gone outside of Anderson to find unbent barbs, if that person believed (as the Examiner apparently does), that Anderson teaches unbent barbs in the first place. It defies logic to suggest, as the Examiner does, that one of ordinary skill would have read Anderson and believed that it disclosed unbent barbs, and then would have sought **another, separate reference** to provide unbent barbs. Because the Examiner failed to provide any proper motivation to combine Boatman, it must be assumed that the Examiner has engaged in improper hindsight.

In any event, Boatman does not make up for Anderson's deficiencies. The Examiner cites paragraphs 24, 81, and 84 of Boatman for the proposition that stents may be designed to provide bending "over only certain curvilinear struts, while other sections of the stent do not deform." See Final Office Action at p. 5. He also concludes, without any support, that it would have been obvious to one of ordinary skill in the art to "remove[] material only along the thicker curvilinear struts 12 [of Anderson] such that the arches 18 bend outwardly to direct the barbs 20 to face outwardly (as shown in figure 7 of Anderson)." See *id.* (emphasis added). Excepting hindsight, the Examiner has absolutely no basis for these assumptions.

These assumptions are undermined, in any event, by the actual teachings of Anderson and Boatman. In particular, paragraph 84 of Boatman discloses that prior art stents "plastically deform at points of stress," whereas what Boatman describes is "distribution of the lateral bending forces over the curvilinear struts of the present invention." See Boatman; ¶84. Thus, contrary to the Examiner's assertion, paragraph 84 appears to **teach away** from the Examiner's proposal to provide points of

stress in the Anderson stent by selectively removing material from some portions of Anderson's cylindrical rings 12, but not others.

Moreover, the Examiner's conclusion that one of ordinary skill would have removed material only along the thicker curvilinear struts suggests that the Examiner believes that the skilled artisan would not have removed material in the area of the barbs 20. This directly contradicts Anderson's express teaching of step etching "in the areas of the attachment elements or barbs 20 . . . so that the barbs will bend outwardly when the stent is expanded." See Anderson; col. 9, lines 16-22; Final Office Action at p. 4 (the Examiner recognizes that "Anderson further teaches stent material is removed at selective locations near the barbs to yield desired bending of the stent . . .") (emphasis added). Again, the Examiner ignores the Board's findings in this case. See Board Decision at p. 4 ("Anderson further teaches using 'step etching' in the area of barbs 20 so as to, . . . remove portions of the material so that ***the barbs will bend outwardly*** when the stent is expanded.") (emphasis in original).

Neither Anderson nor Boatman, alone or in combination, discloses, teaches, or suggests a stent with each and every feature recited in the present claims. Moreover, the Examiner has failed to establish that one of ordinary skill would have been motivated to combine Boatman. Thus, the Examiner has failed to establish a *prima facie* case of obviousness and the present rejection is improper.

III. CONCLUSION

Applicant believes that claims 45, 46, 48-50, 53, 58, and 60-62 are patentable and that the application is in a condition for allowance. Applicant respectfully requests that the Examiner withdraw the current rejection and allow the claims to issue. The Examiner is invited to contact the undersigned attorney via telephone if such communication would expedite this application.

Respectfully submitted,

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